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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,189	06/03/1999	MASATAKA KINJO	990360/LH	2516

7590 12/04/2001

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/325,189

Applicant(s)

Kinjo

Examiner

Joyce Tung

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 24, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) 9-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1-8 and 39-43 is/are rejected.
- 7) ☒ Claim(s) 41-43 is/are objected to.
- 8) ☒ Claims 1-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. .
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). .
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). . 20) ☐ Other:

Art Unit: 1656

## DETAILED ACTION

### *Continued Prosecution Application*

1. The request filed on 9/24/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/325,189 is acceptable and a CPA has been established. An action on the CPA follows.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-8 and 39-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 2-8 and 39-43 are vague and indefinite because it is unclear in claim 2 whether or not the amount of the marker molecule measured is attached on the target nucleic acid or the amount of the marker molecule measured is in the solution. It is suggested to clarify uncertainty.
- b. Claims 5-8 and 39-43 are vague and indefinite because the language "the converting" in claim 5 has no antecedent basis from where it is referred.

Art Unit: 1656

- c. Claims 7-8 and 39-43 are vague and indefinite because the language "molecule" in claim 7 is unclear what is the molecule. Does it mean that the molecule is the marker molecule attached on the target nucleic acid. It is suggested to clarify uncertainty.
- d. Claim 6 is vague and indefinite because of the language "the measuring of the signal is performed in a state of noncontact with the test solution". It is unclear how the signal is measured in a state of noncontact with the test solution.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 1-8 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Eigen et al. (5,807,677).

Eigen et al. disclose a method for the direct identification of single nucleic acid strands of a specific target sequence (See the Abstract). The method involves fluorescence correlation spectroscopy (FCS) in which the target nucleic acid is amplified with PCR (See column 3, lines 46-57). This is inherent that a forward primer and a reverse primer are used in the reaction as recited in the limitation of claim 1(a) and the primer is marked with one or more dye molecules

Art Unit: 1656

(See column 2, lines 31-32 and column 4, lines 25-28) (as recited in claim 39). This is inherent that the number of labeled primer molecules is known (as recited in claim 39). The fluorogenic molecules can be measured in extremely diluted solution (See column 2, lines 39-42). Eigen et al. also disclose that alternatively, it is also possible to produce the dyed double strand of nucleic acid to be identified through a direct polymerization of the nucleic acid strand to be identified, whereby dyed nucleic acid mononucleotides are used and marked UTP's are preferably used (See column 5, lines 54-59) (as recited in claim 1 (a) and specification, pg. 467, lines 5-8). Thus, the teachings anticipate the limitations of claims 1-8 and 39.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eigen et al. (5,807,677) as applied to claims 1-8 and 39 above, and further in view of Gyllensten et al. (Proc. Natl. Acad. Sci. USA, 1988, Vol. 85, pg. 7652-7656).

The teachings of Eigen et al. are set forth in section 5 above and Eigen et al. do not disclose using asymmetric nucleic acid amplification.

Art Unit: 1656

Gyllensten et al. disclose using asymmetric amplification to amplify a single copy gene (See pg. 7652, the Abstract) (as recited in claim 40).

One of ordinary skill in the art would have been motivated to perform the amplification step by using asymmetric nucleic acid amplification as taught by Gyllensten et al. because the method of Gyllensten et al. produces an excess of full-length single-stranded DNA of a chosen strand that is suitable for sequence determination (See pg. 7652, first paragraph). It would have been prima facie obvious to carry out the method as claimed.

***Allowable Subject Matter***

8. Claims 41-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this office action and any intervening claims.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

Art Unit: 1656

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

November 30, 2001

A handwritten signature in black ink, appearing to read "E. Campbell". The signature is stylized with a large, looped "E" and a cursive "Campbell".

**EGGERTON A. CAMPBELL  
PRIMARY EXAMINER**